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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David Deperthes

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,977	<b>Applicant(s)</b> DEPERTHES ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-10,12,17,28-30,41-46 and 49-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-10,12,17,28-30,41-46 and 49-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 6, 43, 44, and 49 have been amended.  
Claims 5, 13-16, 21, 23-27, 31-38, 47, and 48 have been cancelled.  
Claims 50-68 have been added.
2. Claims 1, 4, 6-10, 12, 17, 28-30, 41-46, and 49-68 are under examination.
3. The following office action contains NEW GROUNDS of Objection.

### ***Drawings***

4. The drawings were received on November 16, 2007. These drawings are accepted.

### ***Objections Withdrawn***

5. The objections to the drawings are withdrawn in view of applicant's amendments to the drawings.
6. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

***Rejections Withdrawn***

7. The rejection of claims 1, 4, 6-10, 17, 44-46, and 49 under 35 U.S.C. 103(a) as being obvious over Houimel, et al. in view of Azevedo, et al. is withdrawn in view of applicant's amendment to the claims.

8. The rejection of claims 1, 4, 6-10, 17, 28-30, 44-46, and 49 under 35 U.S.C. 103(a) as being obvious over Houimel, et al. in view of Azevedo, et al. and further in view of Goins, et al. is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

9. The rejection of claims 1, 4, 6-10, 12, 17, 28-30, 41-46, 49 and newly added claims 50-68 under 35 U.S.C. 112, first paragraph as lacking enablement is maintained.

The response filed November 16, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the claims have been amended to require that the portion of the COMP have a specific functional characteristic, i.e., that the COMP portion can oligomerize. As described at page 19, lines 16-32, the COMP region of the peptabody imparts the ability of the protein to oligomerize. Applicant provides working examples of peptabodies that contain such COMP sequences. With respect to the hinge portion of the claimed peptabody, Applicant submits that one of ordinary skill in the art would be able to make and use the claimed invention without undue experimentation. The specification teaches that the hinge is used as a spacer between protein domains. The specification provides an example of such a spacer, i.e., a 19 amino acid hinge derived from an Ig. Regarding the questions posed by the

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Examiner at page 7 of the Office Action, Applicant provides the following. The first question asked whether the peptabody comprising any of the ligands would bind to an EGF-R. Applicant notes that claims 1, 6, 43, 44, 49 and new claims 51 and 59, each require that the EGF receptor ligand portion of the peptabody be able to bind the EGF receptor. At page 18, lines 23-31, the specification describes characteristics of functional forms of EGF ligands. The second question posed by the Examiner asked whether the length of the polypeptide portions would affect the folding or function of the claimed peptabody. As stated above, Applicant describes the hinge as a spacer between the domains, and also provides a working example of such a linker, i.e., a 19 amino acid hinge derived from an Ig. One of ordinary skill in the art would recognize that such a linker could be replaced in sequence and/or length without undue experimentation. Furthermore, the specification teaches that it is the position of the linker that is significant in achieving the invention (see page 20, lines 7-14). Applicant notes that claim 41 is specific to the enhancer sequences identified in the instant specification. Appropriate clarification with respect to the enablement rejection in view of this claim is respectfully requested.

In response to this argument, regarding the functional language in the amended claims, the as-filed specification does not define the portion of a cartilage oligomer matrix polypeptide (COMP) which is capable of oligomerizing; therefore, one of skill in the art would not know which portion of the polypeptide to use in the peptabody. Additionally, regarding the hinge, applicant notes that the position of the linker (hinge) is important in the invention. The location of the hinge would be different depending upon

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the portion of the COMP included in the molecule and upon the length of the hinge.

Thus, the portion of the hinge is important to the structure and the functionality of the peptabody molecule. Further, the specification discloses that the enhancer affected the amount of peptabody or decabody produced (page 46 examples 6 and 7). Therefore, the specific protein structure of the entire peptabody is important for its functionality, as supported by the references cited in the previous office action.

Regarding claim 41, this claim was included in the enablement rejection for claiming an enhancer sequence which Wickham, et al. (as cited in previous office action) teach as a ligand for integrin substrate, not an enhancer. As such, one of ordinary skill in the art would not expect the sequence, nor variants or chimeras thereof to function as an enhancer.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

### ***NEW GROUNDS of Objection***

#### ***Claim Objections***

10. Claims 1, 41, 43, 44, 49, and 59 are objected to because of the following informalities: the claims contain sequences without reference to SEQ ID Nos. The SEQ ID Nos. need to be included with the sequences in the claims. Appropriate correction is required.

***Conclusion***

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

February 13, 2008

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643